K102095

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# 510(k) Summary

DEC - 7 2010

**Suspension™ Clavicle Fracture Fixation System**

July 23, 2010

**Submitter/Regulatory Contact:**
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**Sponsor/Manufacturer:**
Suspension Orthopaedic Solutions, LLC
2635 Riva Road, Suite 100
Annapolis, MD 21401

**FDA Establishment Registration Number:** Pending

**Trade Name, Common Name, Classification:**

Device Trade Name: Suspension™ Clavicle Fracture Fixation System

Device Common or Usual Names: Bone Plates, Bone Screws

Classification: Class II

Classification Name: Single/Multiple component metallic bone fixation appliances and accessories

Regulation: 21 CFR 888.3030

Product Codes: HRS and HWC

**Predicate Device:**
Smith & Nephew Peri-Loc locking bone plates, locking and non-locking bone screws for the upper extremity – K061352

**Description of the Device:**
The Suspension™ Clavicle Fracture Fixation System is an internal fixation system consisting of various sized plates and screws. The plates and screws are fabricated from 316L Stainless Steel.

The device consists of the following implantable components (some or all of which may be used based on the nature of the injury):

1. Three (3) Sizes of Clavicle Fracture Plate for Each Shoulder (i.e. small, medium, and large; each with Left & Right).
2. Eight (8) Lengths each of 2.7mm Non-Locking & Locking Bone Screws.
3. Eight (8) Lengths each of 3.5mm Non-Locking & Locking Bone Screws.

Implantable components are included in a surgical tray that must be steam sterilized by the hospital or surgical center. These components are intended for re-sterilization, but these components are for single use only.

The implants are used with instrumentation including:

- Hex Driver
  - Handle and a 2.5mm hex driver for hand tightening bone screws
- Assorted Drill bits
  - To create pilot holes for bone screws. The drill bits are compatible with most AO connections.
- Drill Guide Assemblies

**Intended Use:**
The Suspension™ Clavicle Fracture Fixation System can be used for adult patients. Suspension™ Clavicle Fracture Fixation plates and screws are indicated for fixation of clavicle fractures.

**Technological Characteristics:**
The subject devices are substantially equivalent to the predicate devices. Both the subject device and predicate device have indications for clavicle. However, the predicate device also has indications for many other bones (including tibia, femur, pelvis, humerus, metacarpals, etc). The devices are composed of the same materials, and have the same sterility. The devices are used with 3.5mm and 2.7mm locking or non-locking screws.

**Performance:**
The material (316L Stainless Steel) selected is commonly used for orthopedic implants with a long history of biocompatibility.

The devices have been subjected to recognized consensus standards for these types of devices and perform in a manner equivalent to the predicate devices. The device has been subjected to non-clinical testing including Torsional Strength and Break, Four Point Bending, Screw Driving Torque, and Predicate Device Comparison Analysis.

**Conclusion:**
We believe that based on the predicate device comparison and the non-clinical testing performed the subject devices are substantially equivalent to the predicate devices and conclude that the subject devices are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Suspension Orthopaedic Solutions, LLC
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DEC - 7 2010

Re: K102095
Trade/Device Name: Suspension™ Clavicle Fracture Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: November 24, 2010
Received: November 29, 2010

Dear Mr. Raymond:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# Indications for Use

510(k) Number (if known): DEC - 7 2010

Device Name: Suspension™ Clavicle Fracture Fixation System

Indications For Use:

The Suspension™ Clavicle Fracture Fixation System can be used for adult patients. The Suspension™ Clavicle Fracture Fixation plates and screws are indicated for fixation of clavicle fractures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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